PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Casey O'Hara		
Serial No.:	10/092,666	**Examiner:**	K. Schaetzle
Filed:	03/05/2002	**Art Unit:**	3762
Docket No.:	VT0309-US1		
For:	AN IMPLANTABLE MEDICAL DEVICE HAVING A PROTECTED CONNECTION HEADER		

DECLARATION UNDER 37 CFR 1.131

Mail Stop Amendments
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

facsimile transmitted to the
~~I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendments – Fee~~ Patent and Trademark Office:
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450, on:

November 29, 2004

Jeanne Guynes

11/29/04
Date

Sir:

I, Casey O'Hara, declare that:

1) I am the sole inventor of the above-identified patent application.

2) I conceived of the invention, in the United States of America prior to January 31, 2002 (the filing date of the published application US 2003/0144707), as evidenced by the following:

a) prior to January 31, 2002, I submitted a description of the invention on an invention disclosure form to the Legal Department (see **Exhibit A (with date redacted)**);

b) prior to January 31, 2002, a draft patent application was sent to the Legal Department by the drafting attorney, Bennet Langlotz, Esq. (see **Exhibit B (with date redacted)**);

c) prior to January 31, 2002 I personally reviewed the draft patent application, and returned it with comments to the Legal Department for final revision. (see **Exhibit C (with date redacted)**); and

d) a U.S. Patent Application based upon the invention disclosure was filed with the United States Patent Office on March 5, 2002.

3) The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

11/9/04
Date

Casey O'Hara

ALL PURPOSE ACKNOWLEDGEMENT

State of California)
County of San Mateo)

On October 9th, 2004, before me, Kelly Anderson, Notary Public, personally appeared Casey O'Hara, personally known to me OR proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

Witness my hand and official seal.

Signature of Notary

KELLY ANDERSON
Commission # 1514189
Notary Public - California
San Mateo County
My Comm. Expires Sep 18, 2008

ST. JUDE MEDICAL

CARDIAC RHYTHM MANAGEMENT DIVISION

INVENTION DISCLOSURE

FOR PATENT GROUP USE ONLY:

DOCKET NUMBER: VNT021/00

DATE RECEIVED:

RECEIVED BY: SJM

TYPE or PRINT, SIGN and have WITNESSED this invention disclosure form as soon as you have made an invention. If you have any questions, consult the Patent Department and/or the "*Guidelines for Drafting Invention Disclosures.*"

1. TITLE OF INVENTION: Protected ICD header

2. PROBLEM TO BE SOLVED: Briefly describe the purpose or problem your invention is trying to solve, and/or any background or state-of-the-art information.

Current header designs of ICD devices place the header on the upper portion of the ICD can, attached to the can along one or two faces, with an electrical feedthrough to supply the electrical signals through the wall of the can. In this unprotected installation, forces can be exerted on the header which would cause a moment load between the header and the can, creating the possibility of damage to the header or to the integrity of the voltage path within the header.

Moment loads on the header can occur during manufacturing, shipping, handling during installation, and handling during insertion of leads into the header.

3. DESCRIPTION OF THE INVENTION: Provide a complete and concise description of your invention. The description should include (to the extent known at the time of this disclosure): the structure, operation, and physical, chemical, biological, or electrical characteristics, with sketches and/or schematic diagrams where possible. Identify the number of sheets attached which form a part of the disclosure (if any): _____ pages.

This invention places the header in a more protected situation with respect to the device can, by enclosing it more completely. The header could be attached to the can on three, four or five sides, leaving at least one face exposed for lead insertion.

With more faces of the header interfaced with the can, there are more options available for pass through location, to more conveniently or efficiently access the electrical contacts embedded within the header.

4. List advantages and novel features below:

a) Header is securely attached to device can, preventing damage or dislocation due to moment loading.

b) Increased opportunity for electrical interfacing due to more can-header contact faces and increased contact area.

c) Improved ease of molding/forming header to ICD can, using simpler forms and molds.

d) system is safe and unobtrusive to the patient, and may be more comfortable to the patient.

5. Planned uses: (a) This invention will be used in the following products:

(b) This invention could be used in the following products: consolidated platform Tachy devices

6. Clinical or pre-clinical evaluation is scheduled for:

7. The invention is described on pages _____ _____ **of Notebook No.:**

8. Successful test results, if any, were recorded where

9. Is the invention currently under development, in research, or are tests being scheduled:

10. Has there been any publication, sale or public use, or disclosure of this invention to anyone outside of Pacesetter? YES

If "YES", complete the following, as appropriate:

a. Title and date of publication _____

b. Date of first sale _____

c. Date of first public use _____

11. Are you aware of any technical papers, writings, patent applications, or similar disclosure describing this invention? YES

If "YES", complete the following, as appropriate:

a. Has the manuscript been accepted for publication at the time of the disclosure? YES

b. Type of document and title _____

c. Document submitted to _____

d. Anticipated publication or presentation date _____

IDENTIFICATION OF CONTRIBUTOR(S): Please list each person who has **CONTRIBUTED TO THE CONCEPTION** of the invention.

1. Name Casey O'Hara Tel. Ext. 6208 Citizenship USA

Residence 49 Showers Drive #N165 Mountain View Santa Clara CA 9404

Street City County State Zip

Signature _____ Date _____ Supervisor Tim Fayram

WITNESSES: I have **READ** and **UNDERSTOOD** the attached invention, and/or the invention has been explained to me.

Signature of Witness _____ Date _____

Signature of Witness _____ Date _____

GUIDELINES FOR DRAFTING INVENTION DISCLOSURES

The following guidelines were developed to assist in preparing an invention disclosure. Please attempt to briefly answer every item. The intent of the invention disclosure is primarily to provide the Invention Review Committee with a summary of the invention in sufficient detail so that they can determine whether or not to pursue a patent application on the invention or keep it a trade secret.

The invention disclosure form should be typed or clearly printed. Additional pages may be attached to the invention disclosure form as needed. Photocopies of the inventor's notebook pages may be attached, however, a typed description is still preferred to facilitate the invention review process. Illegible disclosures will be sent back to the inventor. Invention disclosure forms are available in Microsoft Word for Windows or on hard copy(see Steven Mitchell).

1. THE TITLE OF THE INVENTION

The title should be a general description of the invention as a whole. Try to keep it simple and brief. It does not have to be drafted in "legalese" and it will probably be changed by the time an application is filed.

2. STATEMENT OF THE PROBLEM

Briefly describe the problem as you understand it or the purpose of the invention. Include any background information or any known prior art solutions. Describe how the problem has been unsolved or unrecognized in the past.

3. DESCRIPTION OF THE INVENTION

The first sentence should be a general overview of the solution provided by this invention so that the Invention Review Committee can easily understand the invention and can decide whether to authorize preparation of a patent application. Include a brief technical description of the invention to support the first sentence. Include all alternate embodiments of the invention known at this time.

Attaching drawings significantly enhances the Board's ability to determine the merits of the idea. Drawings should be made in permanent ink. Alternately, photocopies of pencil drawings will also be accepted. Drawings should be legible, complete, and witnessed (which may be done on the back of the invention disclosure form). Disclose all necessary drawings to support the written invention disclosure. You may include sketches, notebook pages, and engineering or production drawings, if available. You may include drawings of the prior solutions, if known. Preferably, drawings should describe the concept without quantitative values *unless a quantitative relationship is a significant part of the inventive concept.* For example, you may exclude resistor, capacitor, and inductor values on an electrical schematic unless the values are critical. For mechanical drawings, include all views of the invention necessary to understand it. Relative proportions of the parts and spatial relationships generally need not be accurate and may be roughly approximated.

4. LIST ADVANTAGES AND N OVEL FEATURES

This section identifies the novel features and advantages of the invention and is intended to help "sell" the idea to the Invention Review Committee. Examples include: cost reduction, ease of manufacturability, self-tooling, physiological advantage, superior strength, ease of use, superior performance over the art, etc.

5. PRESENT OF FUTURE PRODUCTS

This section identifies products that will be and/or could be used with this invention. Inventions that have been identified as being incorporated into a product enable the Board to quickly focus on the merits and patentability of the invention and, consequently, will receive a higher priority in preparing an application.

6. CLINICAL OR PRE-CLINICAL EVALUATION

This section identifies products that use this invention and are/or will be in Clinicals. Identification of these inventions enables the Board to quickly focus on the merits and patentability of the invention and, consequently, will receive the highest priority (A+) in preparing an application.

7. ENGINEERING NOTEBOOK IDENTIFICATION

This section provides a paper trail of where to find the earliest description of the invention.

8. SUCCESSFUL TEST RESULTS

Preliminary successful test results enable the Board to determine the feasibility and/or operability of the device.

9. INVENTION UNDER DEVELOPMENT

This section identifies products that are currently under development. Such inventions receive closer scrutiny and attention by the Board to quickly focus on the merits and patentability of the invention and, consequently, will receive a higher priority in preparing an application.

10. PUBLICATION, PUBLIC USE, OR ON SALE

This section must be completed to prevent any intervening bar to receiving a patent. In general, an application has one year after a publication or an offer for sale is made to submit an application in the U.S. However, all foreign rights are lost if a publication or sale has been made prior to filing a patent application.

11. TECHNICAL PAPERS

This section further identifies any publication that Pacesetter will make regarding the invention. In general, it is the Company's policy to file patent applications before any publication has been made. Please consult with the Legal Department before any such publication or presentation of the invention.

IDENTIFICATION OF CONTRIBUTORS

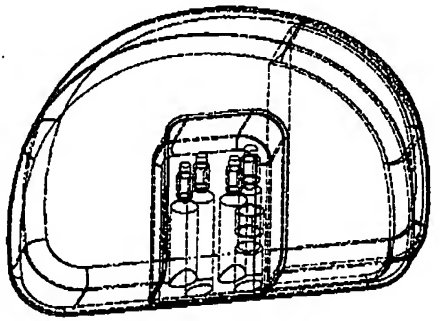
Anyone who has contributed to the concept of the invention, helped to make it operable, or has made practical suggestions that are essential to the invention, may ultimately be added as inventors. The final decision is based on the invention ***as claimed***. A patent can be held invalid if it is determined that there was deceptive intent in not naming all the correct inventors. As such, the originator is responsible for identifying all the contributors to the invention.

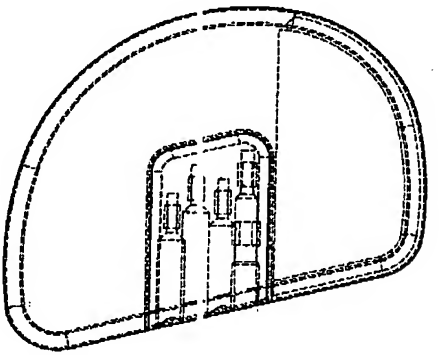
WITNESSING

Find two witnesses who are capable of understanding the invention, and have them sign and date the invention disclosure form.

The witnesses should not be a co-inventor of the invention. Thus, the inventors should select a witness who will not possibly be named as a co-inventor.

Exhibit A





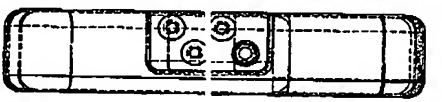


Exhibit A